PAPER#

REISSUE

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Beelman et al.

Reissue Serial No.: 09/899,090

Examiner:

Tierney, Christine

Filed: July 5, 2001

Art Unit:

1700 (Special Programs)

U.S. Patent No. 5,919,507

For:

PRESERVATION COMPOSITIONS AND METHODS FOR

MUSHROOMS

Via Facsimile (703) 872-9743

Attn: Examiner Christine Tierney Commissioner for Patents Alexandria, VA 22313-1450

REQUEST FOR CONSIDERATION DURING REISSUE

Dear Commissioner:

The issue of whether the applicant in this reissue has actually disclosed and enabled its broadened reissue claims under the requirements of 35 USC §112 does not appear to have been fully considered by the USPTO. In filing the reissue request, the patentee added 29 new claims, the broadest of which, claim 9, exceeds the scope of any of the originally issued claims. Other claims also exceed the scope of original claims.

¹ This conclusion is made based on the record available to the undersigned. The entire record was last checked at the end of February, 2003. During a recent attempt to copy the most recent documents of the record, the undersigned was denied access to the files because of their current status (being reviewed in the Special Programs Group of Technology Center 1700). Accordingly, the undersigned cannot determine the current wording of the claims actually under consideration.



9. A method for preserving fresh and processed musbrooms comprising the following steps of:

contacting the mushrooms briefly with an antimicrobial buffer solution having a pH of at least about 9; and

rinsing the mushrooms one or more times after said contacting step with a pH-neutralizing solution having a sufficient pH to return the mushrooms to the mushroom physiological pH or about 6.5.²

In the original reissue request, the patentee stated that the broadened reissue claims were disclosed and supported and provided a document purporting to identify support for the added and broadened claims.³ However, careful examination of the specification as a whole and of the "support section" identified by the patentee will show that at least the broadest of the new claims (i.e., those that attempt to eliminate use of erythorbate buffers in the wash step immediately after the high pH step) are in fact neither disclosed nor enabled.

FACTS RELEVANT TO REISSUE FILING

This reissue filing and the broadening of the claims were apparently caused by the filing of another patent application at the USPTO after the '507 patent was granted. That other application has now issued as U.S. Patent No. 6,500,476 to Martin et al. (the "'476 patent") and is assigned to EPL Technologies, Inc. ("EPL") of Philadelphia, PA. A copy of the EPL '476 patent is enclosed as Exhibit A. The '476 patent discloses a three-step wash method for cleaning and preserving mushrooms.

EPL was apparently working with Pennsylvania State University ("Penn State;" the assignee of the '507 patent) during the preparation and prosecution of the application leading to the '507 patent. As evidence of this relationship, a copy of a letter from Matthew Smith of the licensing office of Penn State to a potential licensee is enclosed (redacted to avoid identifying the potential licensee) as Exhibit B. This letter states that

² '507 patent reissue file history; original request for broadened claims.

³ '507 patent reissue file history; Combined Reissue Application Declaration of the Inventor and Power of Attorney, p. 1, and Statement of Claim Support and Status.

the claims of the '507 patent were drafted by "EPL's counsel" (second paragraph of Exhibit B). This relationship is evidence of the working relationship between the two parties and supports the understanding of the undersigned that Penn State knew about the filing of the EPL patent and that such filing triggered this reissue. There is additional evidence of this triggering event, which can be provided to the USPTO should it consider the triggering event relevant to the issue described herein.

For the record, it should be noted that the undersigned does not represent either Penn State or EPL.

After the grant of the Penn State '507 patent, EPL appears to have realized that the '507 patent process is not particularly valuable from a commercial perspective. EPL then developed a commercially viable three-stage washing process that was not disclosed or claimed in the '507 patent. EPL's recognition of the failure of the '507 patent to describe a commercially viable process is highlighted in the text of the granted EPL '476 patent:

In 1999, Beelman and Duncan incorporated the use of a high pH wash with an antibrowning solution in a two-stage process (U.S. Pat. No. 5,919,507). The Beelman-Duncan process used a high pH first stage as the antimicrobial treatment and a second stage of sodium erythorbate, calcium and EDTA to minimize enzymatic browning. While this process combined and improved the teaching of McConnell and Sapers, it narrowly focused on a two-stage sequence with limited chemical selection in each process step. Specifically, the Beelman-Duncan process limited the pH neutralizing step to include solutions of erythorbic acid and sodium erythorbate. In addition, Beelman applied the erythorbic solution immediately after the antimicrobial contacting step. This restrictive sequence resulted in the rapid degradation of the sodium erythorbate solution in the neutralization stage and the need for increased quantities of the anti-browning materials. Consequently, the Beelman process did not address the variability in raw material and proved too expensive to be adopted by the processors and did not achieve commercial viability.4

It is to "cure" the original claims of the Beelman (Penn State) '507 patent that the current reissue was apparently filed. This is evident from the reissue declaration, which contains the following statement:

^{4 476} patent, col. 2, lines 33-51.

Applicants' attorney failed to appreciate the full scope of applicants' invention. The invention set forth in claim 1, the sole independent claim in the patent, unduly limits the pH-neutralizing solution used in the second stage washing step(s) to a preferred embodiment of buffer solutions of erythorbic acid and sodium erythorbate. The invention described and enabled in the specification is not limited to the used of erythorbic acid/sodium erythorbate buffer solutions to return the final mushroom pH to the physiological range of approximately 6.5. As described in the specification, acidulants and even water alone were used to neutralize the effects of exposure to high pH antimicrobial solutions in the first stage.⁵

While the undersigned agrees that part of this statement is true (i.e., the original granted claims are limited to use of washing steps containing an erythorbate buffer to reduce the high pH first step used to kill bacteria), other parts are inaccurate (and might even be considered misleading). Various inaccuracies are discussed below. However, they can be summarized as follows: All of the wash steps actually shown in the '507 specification and identified as producing useful results (either as specific processes or through generic language) use erythorbate buffer in the wash steps immediately after the initial high pH step. No buffer or acidulant other than an erythorbate buffer is ever described in the specification for use in the wash step after high pH treatment, and the only other wash that is described — water in one comparative example — is described as producing unsatisfactory results.

LACK OF DISCLOSURE AND ENABLEMENT OF BROADENED REISSUE CLAIMS

What the patentee in the '507 patent is attempting to do now, at least by the originally submitted broadened claims, is to eliminate the need to use an erythorbate buffer in the wash step(s) immediately after the initial high pH wash that is used to kill bacteria. It is attempting to claim any process used to reduce the pH in a second step (see claim 9, above). However, the '507 specification teaches no buffered wash solution or

⁵ Page 1 of Combined Reissue Declaration by the Inventor and Power of Attorney in current reissue file history. Note reference here to "Applicants' attorney" in the same context that Exhibit B (above) refers to "EPL's counsel."

acidulant other than erythorbic acid/sodium erythorbate solutions and only uses water in one comparative example said to produce unsatisfactory results.

In that comparative example, water, without any additional buffering, was used, but the results were not considered to be satisfactory. In the second paragraph of the "Conclusions" recited at the end of the patent specification (just before the tables that precede the claims), the specification says that "the erythorbic acid concentration could be reduced to as low as 0.4% and sodium erythorbate concentration as low as 1.6% (retaining the 1:4 erythorbic acid: sodium erythorbate ratio) in the second-stage wash." There is no indication that the erythorbate buffer can be eliminated in the second wash step, which the patentee is now attempting to do in this reissue. This quoted selection from the conclusions is in a paragraph specifically directed to effective treatments: "The treatment was found to be robust, however, and was effective over a range of temperatures, holding times, and even wash solution ingredient concentrations." There is no indication in the specification that the "treatment" was "effective" (i.e., useful) for different wash solution ingredients, as the broadened reissue claim are attempting to encompass.

For convenience, the "Conclusions" section of the specification is reproduced here in its entirety.

CONCLUSIONS8

A two-stage wash treatment consisting of a 0.05M sodium bicarbonate buffer at pH 10.5-11.0 in the first stage, followed by a neutralization solution containing 0.6% erythorbic acid, 2.4% sodium erythorbate, 1000 ppm EDTA, and 1000 ppm calcium chloride in the second stage is very effective at improving shelf life and quality of fresh and processed white mushrooms (Agaricus bisporus). This treatment equals the initial whiteness achieved by sulfite treatment, while controlling bacterial growth, preventing blotch and lesion formation, and improving shelf life and storage quality as effectively as or better than wash treatments incorporating hydrogen peroxide and EDTA.

^{6 &#}x27;507 patent; col. 18, lines 36-41.

⁷ '507 patent; col. 18, lines 30-33.

^{4 &#}x27;507 patent; col. 18, lines 10-67.

Wash solution temperatures and mushroom holding times in wash solutions affect the performance of the high-pH/erythorbate treatment. A retention time of 30 seconds in a pH 10.5-11.0 first-stage buffer at 25.degree. C., followed by 60 seconds in a 3% erythorbate solution at 10.degree. C. were determined to be optimal processing conditions. The treatment was found to be robust, however, and was effective over a range of temperatures, holding times, and even wash solution ingredient concentrations. The pH of the first-stage wash solution could be reduced to 9.5-10.0 without serious detriment to performance, particularly if the buffering capacity (sodium bicarbonate concentration) is increased. Similarly, the erythorbic acid concentration could be reduced to as low as 0.4% and sodium erythorbate concentration as low as 1.6% (retaining the 1:4 erythorbic acid: sodium erythorbate ratio) in the second-stage wash.

The addition of 1000 ppm EDTA and 1000 ppm calcium chloride to the second-stage wash solution enhanced the performance of the treatment, with each ingredient resulting in an improvement in mushroom color. EDTA functions to chelate copper, a cofactor of polyphenol oxidase, the browning enzyme in mushrooms. It has also been shown to enhance the performance of antimicrobials. Calcium chloride may function by increasing solute concentration at the mushroom cap surface, making less water available to bacteria and increasing surface light reflectance (whiteness). In addition, it may improve vacuolar membrane integrity, making the mushroom tissue more resistant to bruising and senescence.

The high pH of the first-stage wash is designed to destroy bacteria on the mushroom cap surface, particularly the phytopathogenic fluorescent pseudomonads, which cause blotches and lesions. Erythorbic acid and sodium erythorbate, in addition to returning mushroom pH to physiological range, act as antioxidants, inhibiting enzymatic browning.

In addition to effectively improving the quality and shelf life of fresh mushrooms, high-pH/erythorbate treatment is useful as a pretreatment to improve the color of canned and frozen mushrooms.

This section presenting "Conclusions" of the inventors in the '507 patent corresponds precisely to the subject matter originally claimed and granted: use of a high pH solution to kill bacteria followed by immediate use of an erythorbate buffer to both neutralize the initial basic solution and inhibit enzymatic browning.

It should be noted, by the way, that despite the language used in the reissue declaration about being unduly limited, the patentee was not limited to the actual preferred embodiments in the originally granted patent. Erythorbate buffers are required, not preferred; preferred embodiments are mixtures of erythorbate buffers with other substances and/or use of erythorbate buffers at preferred concentrations.

In addition to the "Conclusion" section recited above (in its entirety) that requires the use of an erythorbate buffer, the specification states at other locations that the comparative examples (including the one use of water after a high pH step) are unsatisfactory. This is clearly shown in the following selections from the '507 patent, taken from the Summary of the Invention and Experimental sections:

SUMMARY OF THE INVENTION

The present invention provides a sulfite alternative employing high pH (preferably 10.5-11.0) to control bacterial growth on mushrooms, and browning inhibitors to minimize enzymatic browning of mushroom tissue.

High pH (9.0 or above) has been shown to be effective for controlling the growth of bacteria in egg washwater (Catalano and Knabel, 1994). The present invention adapts high-pH solutions as an antimicrobial wash treatment for fresh mushrooms, to prevent bacterial decay of mushroom tissue and resultant tissue browning. With their high susceptibility to tissue damage, mushrooms represent a unique application of high-pH preservative treatments. Solution exposure time must be carefully controlled, to optimize bacterial destruction while avoiding counterproductive overexposure of mushrooms to extremes of pH, resulting in chemical damage to tissue. Thus, the present invention comprises a multiple (two- or three-) stage wash procedure, with an initial high-pH antimicrobial step, followed by one or more pH neutralization/browning inhibitor washes, with an erythorbic acid/sodium erythorbate buffer with EDTA added, for example.

The present invention provides a high-pH treatment for the control of bacterial spoilage of mushrooms. A first-stage, high-pH wash destroys bacteria, but might also directly damage mushroom tissue. This is avoided, however, if mushroom exposure time to the high-pH solution is brief and is followed immediately by a second-stage neutralization buffer, consisting primarily of the enzymatic browning inhibitors erythorbic acid and sodium erythorbate.⁹

Tribasic Sodium Phosphate Trials

In preliminary experiments, solutions of tribasic sodium phosphate (trisodium phosphate, TSP), were used to generate a washwater pH of 11.0 or higher, as a one-stage wash or in combination with water or the enzymatic browning inhibitors erythorbic acid or sodium erythorbate, in a second-stage wash solution.

⁹ '507 patent; col. 2, line 49, through col. 3, line 12.

Use of 10% TSP by itself, in a wash lasting 120 seconds, was destructive to mushroom pileal tissue, yielding a Day 0 whiteness (L) value of 60.42, vs. 93.36 for a reverse-osmosis water wash and 95.10 for a 1000 ppm sodium metabisulfite wash (Appendix Table 1). TSP-washed mushrooms were dark brown in color and slimy in texture, compared to the bright white, dry, firm sulfite control mushrooms. Reduction of mushroom exposure time to TSP from 120 seconds to 60 seconds, followed by a reverse-osmosis-water wash of 60 seconds dramatically improved color, giving a day-0, L-value of 80.22.

Replacing water with a 2.25% sodium erythorbate solution in the second-stage wash yielded a further improvement in color, to an initial (Day 0) L-value of 89.23. When 2.25% sodium erythorbate was replaced with an equal concentration of erythorbic acid, initial whiteness was higher still, with a day-0, L-value of 90.71. Increasing erythorbic acid concentration from 2.25% to 4.50% gave very little improvement in color through day 3, but on day 6, the increased erythorbic acid treatment was noticeably better, with an L-value of 89.50, versus 84.12 for the 2.25% erythorbic acid treatment. Reduction of TSP concentration from 10% to 5% in the treatments with water as the second-stage wash improved color on days 0, 3, and 6.

None of the experimental treatments matched the whiteness of the sulfite and water controls through Day 3, but the two-stage treatment with 4.50% erythorbic acid as the second-stage wash was significantly better than the water-washed control and not significantly different from the sulfite-washed control on Day 6.

Development of a Two-Stage, High-pH/Neutralization Wash Treatment

Results of the trisodium phosphate wash trials indicated that the quality of mushrooms washed in basic-pH antibacterial solutions could be improved by subsequent transfer to a neutralization solution of erythorbic acid and sodium erythorbate. Erythorbate solutions acted as both an antioxidant, slowing the enzymatic browning reaction, and an acidulant, returning final mushroom pH to physiological range (approximately 6.5), thus minimizing tissue damage due to exposure to high pH. 10

Language describing the two desired functions of the erythorbate buffer in the wash (immediately lowering pH while concurrently and immediately providing antibrowning effects) also appear at numerous other locations in the specification. The examiner is invited to review the specification as a whole, as well as the selections recited above, after which it will be apparent that the only workable process described in the

^{10 &#}x27;507 patent; col. 8, line 57, through col. 9, line 27.

'507 patent is one that uses an erythorbate buffer wash immediately after the high pH antibacterial step.

It should also be noted that "immediate" use of an erythorbate buffer (i.e., without an intervening wash step and without intervening time) is all that is disclosed in the '507 specification. No intervening step is every shown or described. *Immediate* use of erythorbate buffer is critical, as stated by the patentee:

A first-stage, high-pH wash destroys bacteria, but might also directly damage mushroom tissue. This is avoided, however, if mushroom exposure time to the high-pH solution is brief and is followed immediately by a second-stage neutralization buffer, consisting primarily of the enzymatic browning inhibitors erythorbic acid and sodium erythorbate.¹¹

Since the process is designed to avoid damaging mushrooms and since the high pH wash can damage them, "immediate" application of an erythorbate buffer that avoids both high pH damage and browning produces satisfactory results. There is no indication anywhere in the specification that the desired elimination of both high pH damage and mushroom browning (two different processes, as explained in the specification) can be avoided without "immediate" use (i.e., without intervention of either time or another step) of an erythorbate buffer.

That the '507 patent does not describe a process of lowering pH with acidulants other than an erythorbate buffer, followed by a third step using a combination of any browning inhibitor (including an erythorbate buffer) and a chelating agent (such as EDTA), is a decision already reached by the USPTO. The EPL '476 patent was recently granted with the following broadest claim:

1. A method for preserving mushrooms comprising the steps of:

contacting the mushrooms with an aqueous anti-microbial solution having a pH of from about 10.5 to about 11.5;

rinsing the mushrooms at least once with at least one aqueous pH neutralizing buffer solution comprising organic acid and at least one salt

^{11 &#}x27;507 patent; col. 3, lines 5-12.

of an organic acid and substantially free from erythorbic acid and sodium erythorbate; and

contacting the mushrooms at least once with at least one solution comprising a browning inhibitor and a chelating agent.¹²

If such a process had been described in the specification of the '507 Penn State patent, the '476 EPL patent should not have been granted. However, the '476 patent was granted, despite the '507 patent having been considered specifically as prior art against the '476 patent (see the face of the '476 patent). Since the '507 patent clearly shows immediate use of an erythorbate buffer and the chelating agent EDTA (see example in column 10 of the '507 specification), there has already been a USPTO decision that the use claimed by EPL in the '476 patent (i.e., use of other acidulants to neutralize the first high pH step, followed by a third wash with an erythorbate solution, or another material that acts as an antioxidant, along with a chelating agent) is not disclosed in the '507 patent.

The patentee in the '507 reissue may wish that the specification discloses something beyond its original content, but a mere wish to encompass additional subject matter does not entitle a patentee to broadened reissue claims that have been expanded beyond the scope of the original disclosure so that they have an unwarranted monopolistic economic effect.

CONCLUSION

That which is not disclosed and enabled cannot be claimed. The '507 patentee is attempting to enlarge its claims to cover subject matter not originally disclosed or enabled in order to obtain an economic advantage to which it is not entitled, based on the specification in question. Such a request should be denied.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at his direct telephone extension: (650) 843-5070.

^{12 &#}x27;476 patent; col. 18, lines 54-64.

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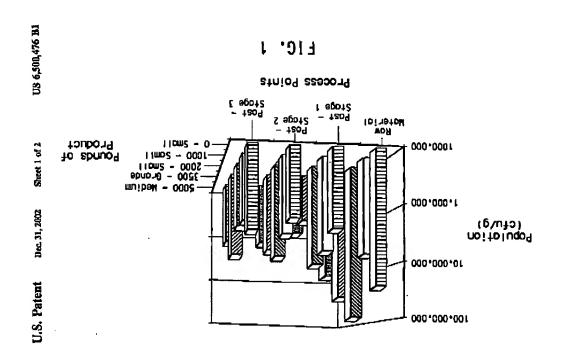
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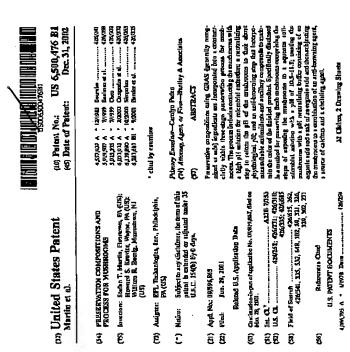
Respectfully submitted, COOLEY GODWARD LLP

By:

Richard L. Neeley, Ph.D.

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TABLE 1

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Marthew D. Smith Technology Licensing Officer Intellectual Property Office The Pennsylvania State University 113 Technology Center 200 Innovation Bivd. University Park. PA 16802-7000 Office: (814) 865-6277
Direct: (814) 863-1122
Fax: (814) 865-3591
E-mail: mds126@psu_edu
Website: www.ipo.psu.edu

RE:

U.S. Patent No. 5,919,507 (Issued July 6, 1999) and PCT/US98/20728 (Filed October 2, 1998) "Novel Two-Stage Wash Process for Extending Shelf Life of Fresh Mushrooms" Inventors: R. Beelman, et al. PSU Invention Disclosure No. 95-1514

Dear

We received your letter dated / and your inquiry about the University's other technology rights in the area of mushroom treatment.

As you know, PSRF is the owner of US Patent 5,919,507. This patent covers, inter alia, a preferred embodiment of the University's process. However, we believe that the claims drafted by EPL's counsel were not as broad as the invention described and enabled in the patent specification. Accordingly, the University has filed documents at the U.S. Patent and Trademark Office to expand the breadth of the patent.

PSRF has also filed PCT international application PCT/US98/20728 corresponding to the '507 patent. PSRF has entered into the national phase of numerous countries outside of the US based on this application.

The University has also filed a new application covering refinements and improvements to the initially-developed process, including a process different from the two-stage wash claimed in the '507 patent. The resulting patent is expected to cover the results of further research and development conducted by Dr. Beelman's laboratory since the original application was filed.

If is interested in licensing these technologies for either domestic use or international use, we would be willing to provide additional information about the University's latest processes and proprietary rights.

Sincerely,

Matthew Smith

Technology Licensing Officer

/mds